

II. Claims 7-9, drawn to an antibody reactive with the antigenic peptide of primary Group I, classified in class 530, subclass 350. According to the Examiner, a single sequence is also required to be selected from SEQ ID Nos: 1-13 and 21 for which the antibody reacts which should not be construed as an election of species. Thus, primary Group II has been further divided into 14 separate Groups.

III. Claims 10-21, drawn to a nucleic acid molecule encoding a peptide or polypeptide of primary Group I, host cells comprising said nucleic acid, vectors comprising said nucleic acid, and a method of producing the antigenic peptide of primary Group I, classified in class 536, subclass 23.1. According to the Examiner, a single sequence is also required to be selected from SEQ ID Nos: 1-13 and 21 which should not be construed as an election of species. Thus, primary Group III has been further divided into 14 separate Groups.

IV. Claims 32-40, drawn to a method of treating cancer comprising stimulating the production of protective antibodies or immune positive CD4+ cells comprising the administration of the peptides of primary Group I, classified in class 514, subclass 2. According to the Examiner, a single sequence is also required to be selected from SEQ ID Nos: 1-13 and 21 which should not be construed as an election of species. Thus, primary Group IV has been further divided into 14 separate Groups.

The Applicants respectfully traverse the restriction requirement. In order to satisfy the Applicants' obligation under the restriction requirement, the Applicants provisionally elect with traverse primary Group I and SEQ ID No. 1.

In total the Examiner has divided the Application into 56 ($14 \times 4 = 56$) Groups to be filed as 56 separate divisional applications. In contrast to the Examiner's grouping of inventions, the Applicants respectfully note that the claims should not be divided into a

56 Groups (based upon primary Groups I-IV and SEQ ID Nos. 1-13 and 21) because there is no serious burden on the Examiner to examine all the SEQ ID Nos. in each primary Group and because the peptide, antibody, and nucleic acid claims in Groups I, II, and III are linked by a common linking claim.

I. There Is No "Serious Burden" As Defined By The MPEP

Under MPEP § 803, if the search and examination of all the claims in an application can be made without serious burden, the examiner **must** examine such claims on the merits, even though they include claims to independent or distinct inventions. MPEP § 808.02 further states:

[T]he examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required. Thus the examiner must show by appropriate explanation one of the following:

(A) **Separate classification thereof:** This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

(B) **A separate status in the art when they are classifiable together:** Even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search.

(C) **A different field of search:** Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes/subclasses or electronic resources, or employing different search queries), a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and

**field of search, no reasons exist for dividing among >independent or<
related inventions. (Emphasis added).**

A. All The SEQ ID Nos. In Each Primary Group Are Not Classified Separately

All the SEQ ID Nos. in each primary Group (Groups I-IV) are not classified separately. For example, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group I are all classified in class 530, subclass 300. Likewise, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group II are all classified in class 530, subclass 350. Similarly, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group III are all classified in class 536, subclass 23.1. In addition, according to the restriction requirement, SEQ ID Nos: 1-13 and 21 of primary Group IV are all classified in class 514, subclass 2. Accordingly, it is clear (and the Examiner does not appear to dispute the fact) that all the SEQ ID Nos. in each primary Group (Groups I-IV) are not classified separately as required by MPEP § 808.02(A).

B. There Is No Separate Status In The Art

As stated under MPEP § 808.02(B), inventions "classified together can be shown to have formed a separate subject for inventive effort when the examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status . . ."

However, the Examiner has presented no evidence of separate inventive effort or separate status in the art, nor has the Examiner cited any patents asserted to be evidence of such separate status. SEQ ID Nos: 1-13 and 21 of each primary Group are MHC class II associated antigenic peptides and thus have the same status in the art. Accordingly, the Examiner has not shown that the claimed polymorphisms and primers have a separate status in the art as required by MPEP § 808.02(B).

C. The Field of Search Is the Same

The Applicants respectfully submit that the Examiner has not shown a separate field of search for SEQ ID Nos: 1-13 and 21 of each primary Group. According to the specification on page 8, paragraph [0029]-[0030]:

The MHC class II associated novel antigenic peptides of the invention originate from the cytoskeletal protein vimentin (SEQ ID NOs. 1 to 6), the translation factor eIF-4A1 (SEQ ID NOs. 7 to 9), the IFN- γ inducible protein p78 (SEQ ID NOs. 10 and 11) and the iron-binding surface protein melanotransferrin (SEQ ID NOs. 12 and 13) and melanoma antigen recognized by T-cells 1 (MART-1, Melan-A protein; SEQ ID NO: 21).

The single peptide binding groove of MHC class II molecules is about 25 Å long, but in contrast to MHC class I molecules, both sides are open (Stern L J et al., Nature 1994; 368, 215-221). Thus, naturally processed antigenic peptides eluted from human MHC class II molecules have a minimal length of about 11 residues and attain a maximal length of about 25 residues (Chicz R M et al., J Exp Med 1993; 178, 27-47).

Thus, it is clear from the specification that SEQ ID Nos: 1-13 and 21 of each primary Group are MHC class II associated antigenic peptides. Accordingly, the Applicants respectfully submit that the field of search would be the same for all such MHC class II associated antigenic peptides.

Since the search and examination of SEQ ID Nos: 1-13 and 21 of each primary Group can be made without serious burden (as defined by MPEP § 808.02 above), the Applicants respectfully submit that examiner "must examine" all of them on the merits pursuant to MPEP § 803.

II. The Peptide, Antibody, And Nucleic Acid Claims In Groups I, II, And III Are Linked By A Common Linking Claim

In addition, Groups I, II, and III should be combined because the claimed antibodies of Group II are dependent on and defined by the antigenic peptides of Group

I and because the nucleic acid molecules of Group III are dependent on and encode the antigenic peptides of Group I. Thus, the claims in Groups I, II, and III are linked by a common linking claim (claim 1) and thus are inseparable from each other. Pursuant to MPEP § 809, such inseparable linked claims must be examined with and are considered part of the invention elected. MPEP § 809 states:

There are a number of situations which arise in which an application has claims to two or more properly divisible inventions, so that a requirement to restrict the claims of the application to one would be proper, but presented in the same case are one or more claims (generally called "linking" claims) inseparable therefrom and thus linking together the otherwise divisible inventions.

* * * *

The linking claims must be examined with, and thus are considered part of the invention elected.

Therefore, pursuant to MPEP § 809, the linked peptide, antibody, and nucleic acid claims in Groups I, II, and III must be examined with and are considered part of any invention elected.

CONCLUSION

The Application has been divided into 56 Groups to be filed as 56 separate divisional applications. The Applicants respectfully traverse this restriction requirement for the reasons stated above and also believe that the restriction requirement in its current form is inconsistent with Office Policy under the "TC1600 RESTRICTION PRACTICE ACTION PLAN" which is designed to improve the quality and consistency of restriction practices in TC1600 (see the U.S.P.T.O. website at <http://www.uspto.gov/web/patents/restriction1600.htm> and the accompanying training materials at <http://www.uspto.gov/web/patents/tc1600restrictionmaterials.pdf>). If the Examiner makes the restriction requirement final in its current form the Applicants plan to petition the Director under 37 C.F.R. § 1.144 to withdraw the restriction requirement. Accordingly, in such a case, the Examiner may want to consider making the restriction

requirement final without further conducting a search or examining the claims until the Director responds to the Applicants' petition under 37 C.F.R. § 1.144 (in order to avoid any unnecessary work by the Examiner in case the Director agrees with the Applicants or combines certain Groups or otherwise revises the number or definition of the Groups in its current form).

No fee is believed to be required in connection with the filing of this response. However, if any fee is deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



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